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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/532,832

Applicant(s)

MIYAYAMA, TETSUO

Examiner

ABIGAIL FISHER

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,8 and 11-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,5,6,8 and 11-17 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Receipt of Amendments/Remarks on October 8 2009 is acknowledged. Claims 3-4, 7 and 9-10 were/stand cancelled. Claims 1-2, 5-6, 8 and 11-17 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 6, 8-11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicant's amendments filed on October 8 2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-2 and 5 under 35 U.S.C. 103(a) as being unpatentable over Irizato et al. (US Patent No. 5986042) is **withdrawn** in light of Applicant's amendment in the reply filed on October 8 2009.

Modified Rejection Based on amendments in the reply filed on October 8 2009

Claims 6, 8, 11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-354542 (JP '542, cited in the Office action mailed on 8/30/07) in view of Sheppard et al. (US Patent No. 4847078, cited in the Office action mailed on 7/8/09) as evidenced by Kunioka (Kobunshi Ronbunshu, 1993, cited in the Office action mailed on 7/8/09).

Applicant Claims

The instant application claims a cosmetic material comprising an oiliness agent selected from the group consisting of vegetable oils, higher alcohols or esters thereof, higher fatty esters and liquid paraffins; and a cross-linked product of a poly- γ -glutamic

acid and/or a cross-linked product of a poly- γ -glutamic acid salt wherein said cross-linked product of a poly- poly- γ -glutamic acid salt has a particle size of 0.1 to 100 μm and an average particle size of 1 to 50 μm wherein said crosslinked product of poly- γ -glutamic acid or said crosslinked product of a poly- γ -glutamic acid salt are produced by exposing at least one solution selected from the group consisting of an aqueous solution, a methyl alcohol solution and an ethyl alcohol solution of poly- γ -glutamic acid or the poly- γ -glutamic acid salt which contain poly- γ -glutamic acid in an amount of 1 to 30% by mass, to electron beam radiation for crosslinking thereof.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

JP '542 teaches cosmetic compositions comprising poly- γ -glutamic acid. The poly- γ -glutamic acid is formed via radiation. The poly- γ -glutamic acid is dissolved in solvents such as water (paragraph 009) or methanol or ethanol (paragraph 0014) and irritated with radiation to produce a cross-linked poly- γ -glutamic acid (paragraphs 8 and 9). This method is inexpensive and affords a cross-linked poly- γ -glutamic acid with greater moisturizing effect (abstract and paragraph 007). The poly- γ -glutamic acid is utilized in amount from about 0.01 to 5% by weight (paragraph 0016). The poly- γ -glutamic acid is taught as a moisturizer for skin, body and scalp (paragraph 0016). It is taught as being useful for a wide variety of external preparations such as moisturizers, face toilets, and hair gels (paragraph 0017). In a method of making the poly- γ -glutamic acid is taught as being passed through a wire gauze of 80 mesh, and after filtration freeze-dried and the resulting hydrogen absorbs water and swells (paragraph 0019).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While JP '542 exemplifies formation of moisturizers, JP '542 does not specify the inclusion of vegetable oils or fatty alcohols in the compositions. However, this deficiency is cured by Sheppard et al.

Sheppard et al. is directed to topical compositions. The compositions comprise about 5 to about 10% by weight of one or more topically acceptable waxes (column 2, lines 8-9). It is taught that the wax compounds are useful as emollients and humectants in topical applications. That is they aid in softening, moisturizing and lubricating the skin. The presence of these emollients/humectants promotes the production of a cream which does not irritate the skin through abrasion. Waxes taught include cetyl alcohol, stearyl alcohol and jojoba oil (column 2, lines 35-43).

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of JP '542 and Sheppard et al. and utilize a wax component in an amount from about 5 to about 10% in the topical skin formulations. One of ordinary skill in the art would have been motivated to utilize these wax components as they are taught by Sheppard et al. as providing softening, moisturizing and lubrication to topical skin applications and do not irritate the skin. One of ordinary skill in the art would therefore be motivated to add these components to the topical skin compositions taught by JP '542 in order to provide the benefits taught by

Sheppard et al. These benefits would be advantageous to the compositions of JP '542 as the compositions of JP '542 include moisturizer applied to the skin.

Regarding claims 15-17, JP '542 teaches cross-linked poly- γ -glutamic acid. As evidenced by Kunioka, poly- γ -glutamic acid which is prepared via γ -irradiation produces a hydrogen with a specific water content of about 3500 (wt of water/wt of polymer) and a gel content that ranges from 40 to about 90% (abstract and figure 1). Kunioka therefore teaches that it was known in the art at the time of the instant invention that cross-linked poly- γ -glutamic acid is known to swell significantly (i.e. have large absorption ability) as well as the dosage of γ -irradiation changes so does the gel content. Figure 1 additionally shows that as the dosage if irradiation increases, the water content is decreased, which is the same trend seen by Applicants (Table A of Declaration filed 3/17/09).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant argues that the claimed are directed to a crosslinked product having both an average particle size of 1 to 50 microns and a distribution of particle sizes of 0.1

to 100 microns. The desirability of a cosmetic composition including particles falling within two different parameters is not taught or suggested by the cited references.

Applicant's arguments filed October 8 2009 have been fully considered but they are not persuasive.

In the above rejected claims, the particle distribution only pertains to the crosslinked product of a poly- γ -glutamic acid salt. It is noted that the examiner attempted to point this out to applicants in the examiner's notes section, page 2 of the Office action mailed on 7/8/09. Therefore, since the above rejected claims are based on the teachings of a crosslinked product of poly- γ -glutamic acid and not the salt, the claims do not require this particle distribution. Therefore, the rejection of the above claims is maintained for the reasons set forth in the last office action.

Claims 1-2, 5, 8 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-354542 (JP '542, cited in the Office action mailed on 8/30/07) in view of JP 2001-072764 (JP '764, cited in the Office action mailed on 8/30/07) as evidenced by Kunioka and Robinson (US Patent No. 5968500, cited in the Office action mailed on 7/8/09).

Applicant Claims

Applicant claims a cosmetic material comprising a cross-linked product of a poly- γ -glutamic acid and/or a cross-linked product of a poly- γ -glutamic acid salt having a particle size of 0.1 to 100 μm and an average particle size of 1 to 50 μm .

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of JP '542 are set forth above. Specifically, JP '542 teaches cosmetic compositions comprising poly- γ -glutamic acid. The poly- γ -glutamic acid is formed via radiation. The poly- γ -glutamic acid is utilized in amount from about 0.01 to 5% by weight (paragraph 0016). The poly- γ -glutamic acid is taught as a moisturizer for skin, body and scalp (paragraph 0016). It is taught as being useful for a wide variety of external preparations such as moisturizers, face toilets, and hair gels (paragraph 0017). In a method of making the poly- γ -glutamic acid is taught as being passed through a wire gauze of 80 mesh, and after filtration freeze-dried and the resulting hydrogen absorbs water and swells (paragraph 0019).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

JP '542 does not specify a particular particle size of the poly- γ -glutamic acid. However, this deficiency is cured by JP '764

JP '764 is directed to substrates for cosmetics. A cross-linked polyamino acid is used for the base material. The cross-linked polyamino acid preferably has a backbone comprising a homopolymer of polyaspartic acid, polyglutamic acid, or polylysine (abstract, solution). It is additionally disclosed that the polyamino acid can be in the form of an alkaline metal salt, ammonium salt or amine salt (paragraph 37). It is disclosed that the particle size of the poly amino acid will differ according to usage and the purpose of use. When it is used as cosmetics, in order to obtain a slide nature, stretch, and a not rough feeling a size of the polyamino acid utilized is from 10 nm to 500 micrometers, preferred 100 nm to 200 micrometers and more preferred are from 1 micrometer to 100 micrometers (paragraph 0041). Exemplified are particle sizes of 100

micrometers or less (paragraph 0062). The amount of the polyamino acid is from 0.001 to 50% of the weight (paragraph 0050).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of JP '542 and JP '764 and manipulate the particle size of the poly- γ -glutamic acid. One of ordinary skill in the art would have been motivated to manipulate the particle size depending on the desired end use of the cosmetic. Based on the teachings of JP '764 one of ordinary skill in the art would desire to reduce the particle size to between 1 and 100 micrometers in order to provide fine particles which do not provide a rough feel on the skin. Therefore, one of ordinary skill in the art would have been motivated to increase the particle when desiring a cosmetic with a rougher feel (for example an exfoliant) and motivated to decrease the particle size when desiring a cosmetic that has a smooth feel on the skin (such as a moisturizer). As evidenced by Robinson, polymers can be passed through various sieve screens which possess different mesh openings as well as they can be ground or crushed in order to produce desired particle sizes. A 400 mesh sieve screen produces particle sizes of 38 microns (columns 7-8, lines 65-67 and 1-8). Therefore, it is well within the skill of one of ordinary skill in the art to vary the mesh screen that the particles are passed through in order to manipulate the particle depending on what was desired for the particular end use.

Regarding claims 12-14, JP '542 teaches cross-linked poly- γ -glutamic acid. As evidenced by Kunioka, poly- γ -glutamic acid which is prepared via γ -irradiation produces a hydrogen with a specific water content of about 3500 (wt of water/wt of polymer) and a gel content that ranges from 40 to about 90% (abstract and figure 1). Kunioka therefore teaches that it was known in the art at the time of the instant invention that cross-linked poly- γ -glutamic acid is known to swell significantly (i.e. have large absorption ability) as well as the dosage of γ -irradiation changes so does the gel content. Figure 1 additionally shows that as the dosage of irradiation increases, the water content is decreased, which is the same trend seen by Applicants (Table A of Declaration filed 3/17/09).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that none of the combined references do not teach or suggest of the elements of claim 1. Specifically, they do not teach or suggest the desirability of a cosmetic composition including particles falling within two different parameters. It is argued that the JP '542 is completely silent about particle size and JP '764 only teaches a single parameter.

Applicants' arguments filed October 8 2009 have been fully considered but they are not persuasive.

Regarding the claimed particle size, the examiner maintains that based on the teaching of the art one of ordinary skill in the art would have been motivated to manipulate the particle size. One of ordinary skill in the art would expect that larger particles sizes would produce a cosmetic that possess a rougher feel where as smaller particle size would produce those that are more smooth to the touch. Therefore, depending on the end use one of ordinary skill in the art would have been motivated to manipulate the particle size. Additionally, there are various methods for producing the desired particle size. JP '542 teaches passing it through a mesh. As evidenced by Robinson there are a variety of meshes that exist for manipulation of particle size. Therefore, when desiring poly- γ -glutamic acid with a smaller particle size one of ordinary skill in the art would just have to choose a mesh of a different size with smaller openings (say a 400 mesh) in order to produce the desired particle size. JP '764 teaches that when the polyamino acid is used as cosmetics, in order to obtain a slide nature, stretch, and a not rough feeling a size of the polyamino acid utilized is from 10 nm to 500 micrometers, preferred 100 nm to 200 micrometers and more preferred are from 1 micrometer to 100 micrometers. Exemplified are particle sizes of 100 micrometers or less. It is noted that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5].** JP '764 provides the motivation for one of ordinary skill to reduce the particle size in order to reduce the rough feeling. The preferred particle range overlaps the claimed particle size. However, JP '764 does not state the average particle size. However, since JP '764 provides the motivation to reduce the particle size, it provides

the motivation to one of ordinary skill in the art to reduce the particle size from 100 micrometers down to 1. Since the particle size overlaps that instantly claimed, the examiner maintains that a *prima facie* case of obviousness has been established. If applicant believes the average particle is unobvious, then applicant must make of record the reasons it is unobvious. The examiner maintains that the teachings of JP '764 indicate a difference between larger and smaller particle size and their effect on the feel of cosmetic compositions. Therefore, this effect would not be deemed unobvious.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
Art Unit 1616

AF

/Mina Haghighatian/
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